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09/927,933	08/13/2001	Pierre Leroy	032751-066	6916

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	PAPER NUMBER
1632	14

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/927,933	Leroy et al.
Examiner	**Art Unit**
Scott D. Priebe, Ph.D.	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 28, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *40-58* is/are pending in the application.

4a) Of the above, claim(s) *42* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *40, 41, and 43-58* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. *08/809,110* .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

> An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

The reference to 08/809,110 indicates that the present application is a continuation of the '110 application. However, the amendment filed 12/13/01 cancelled all claims directed tot he elected invention in the '110 application and added claims directed to the non-elected invention. Consequently, the instant application is a division of the '110 application. The reference to the '110 application in the first sentence of the specification should be amended to indicate that the instant application is a --division-- of the '110 application.

Information Disclosure Statement

The information disclosure statement filed 8/13/01 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. FR 2706486

has been placed in the application file, but the information referred to therein has not been considered.

The Moritz et al. and Rosenfeld et al. references could not be considered at this time. Applicant indicated that copies of these references had been provided in the '110 application. Review of that application revealed that they had been received by the Office and considered. However, the copies were no longer attached to that application. Applicant is requested to provide copies of these references in response to this Office action so that they can be considered by the Examiner.

Election/Restriction

Applicant's election with traverse of Group VII, claims 40, 41, 43-49, and 51-58 and CD4 as the species in Paper No. 13 filed 2/28/03 is acknowledged. The traversal is on the ground(s) that examination of the other inventions would impose no search burden, the groups are not unrelated, and the cost of examining multiple applications would be higher if the inventions were examined in different applications. This is not found persuasive because while the inventions are classified in the same class and subclass, the patents are not the only prior art searched. As indicated in the restriction requirement, a search of each group is not required for the other groups, and this has proven to be the case. Each of the inventions is directed to an adenviral vector encoding a fusion protein comprising part of an antibody and a toxin or immunopotentiating substance. The toxins and immunopotentiating substances share no common

structures or functions. A search of each invention would require a search of the respective toxin or immunopotentiating substance in the context of the shared features. Consequently, a search of the elected invention, fusion of an antibody and immunopotentiating substance, neither required nor uncovered any art directed to the non-elected inventions wherein the active moiety was one of the toxins of the other groups, e.g. diphtheria toxin. Applicant asserts that the different inventions could be used together. However, the criterion is not simply whether they could conceivably be used together, but whether the specification discloses such use. Applicant has not indicated where the specification teaches using the inventions together. Furthermore, each of the inventions has a different mode of operation, function and effect due to the different toxin or immunopotentiating substance. The remaining issues raised by Applicant, e.g. increased expenditure of time and resources, are not germane to restriction practice.

The requirement is still deemed proper and is therefore made FINAL.

Claim 42, in its entirety, and claims 40, 41, 43-48, and 51-58 as directed to other than a CD4-antibody fusion, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13. As a result of the search of the prior art, claim 50 has been rejoined with the elected invention.

Inventorship

The request to correct the inventorship of this nonprovisional application under 37 CFR 1.48(a) is deficient because:

1) A 37 CFR 3.73(b) submission has not been received to support action by the assignee.

2) It lacks the written consent of an assignee of one of the originally named inventors. Inventor LeRoy appears to be a partial assignee in this application, i.e. there is no evidence that LeRoy assigned his interest in the application to Transgene SA, as has inventor Mehtali.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: .

-- Adenoviral vectors encoding an antibody fused to a CD4 extracellular domain --

Claim Objections

Claims 40, 41, 43-48, and 51-58 are objected to because of the following informalities: These claims embrace non-elected inventions or species, and should be amended to reflect the election. Appropriate correction is required.

Claim 44 is objected to because of the following informalities: recitation of "protein(s)" in line 2 is improper, the term should be --proteins-- . Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 40 is directed to an adenoviral vector which encodes an antibody modified by an immunopotentiating substance. Claim 48, which depends from claim 40, recites that the adenovirus encodes the heavy and light chains of the 2F5 antibody. The claim does not indicate that the 2F5 antibody would be "modified" by an immunopotentiating substance. Consequently, the claims reads on an adenoviral vector which either encodes the fusion of the antibody and immunopotentiating substance and also encodes the heavy and light chains of the 2F5 antibody or encodes a heavy and/or light chain of the 2F5 antibody modified by an immunopotentiating substance. Applicant points to original claims in support for the new claims, however, the original claims do not clearly support the claimed subject matter owing to the improper multiple dependence of these claims. Applicant has not pointed to any specific part of the specification as support for this claimed subject matter. The specification describes retroviral constructs which express unmodified 2F5 heavy and light chain, and an adenoviral vector encoding a fusion of a

CD4 extracellular domain to the hinge region of a 2F5 heavy chain, i.e. the entire 2F5 heavy chain is not present. Neither of these would convey to one of skill in the art wherein an adenoviral vector either encoded separately an antibody modified by an immunopotentiating substance, and 2F5 heavy and light chains or encoding 2F5 heavy and light chains wherein at least one of these was fused to an immunopotentiating substance.

Claims 40, 41, 43-47, and 50-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an adenoviral vector derived from a human adenovirus, does not reasonably provide enablement for an adenoviral vector derived from a non-human adenovirus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 48 and 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 40, 41, 43-58 broadly embrace an adenoviral vectors made from any adenovirus, such as canine, avian, bovine, murine, ovine, porcine, simian adenoviruses and hybrids of these (see claims 44 and 45). The specification mentions such adenoviruses citing non-patent literature disclosing CAV-1, CAV-2, DAV and Bad type 3, but provides no guidance on the construction

of vectors from any adenovirus than human adenovirus type C (e.g. Ad5 and Ad2), and no working examples of such non-human adenoviral vectors are provided. The claims embrace both replication-competent and replication defective vectors. The specification fails to teach where and what type of modifications can be made to any non-human adenoviral genome such that replication competence is either retained or lost. It fails to teach where the exogenous nucleotide sequence may be inserted in such vectors. In the case of replication-defective vectors, it fails to teach cell lines in which the vectors can be made and then propagated so as to produce viral particles.

While vectors derived from human adenoviruses, such as Ad2 and Ad5, were well described in the prior art (see Berkner, Curr. Top. Microbiol. Immunol. 158: 39-66, 1992), there is no evidence of record that adenoviral vectors made from non-human adenoviruses were known to those of skill in the art at the time the invention was made. US 6,294,377 is directed to CAV-2 vectors (see claim 1), and teaches how to make and propagate such vectors. However, this patent issued in 2001, and was filed after the instant invention was made. This patent cannot be used to show that one of skill in the art was aware of how to make CAV-2 adenoviral vectors when the instant invention was made, *In re Glass,* 181 USPQ 31, 34 (CCPA 1974). Its issuance provides evidence that CAV-2 vectors were not known at the time the instant invention was made.

Consequently, in order for one to practice the invention as broadly claimed, one would first have to develop vectors derived from non-human adenovirus and develop methods for propagating them. In the absence or any guidance in either the specification or prior art, undue

experimentation clearly would have been required. In *Genentech Inc. v. Novo Nordisk A/S,* 42 USPQ2d 1001 (CAFC, 1997) , the court held that while the specification need not disclose that which is well known in the art, that this

> general, oft repeated statement is merely a rule of supplementation, not a substitute for an enabling specification. It means that the omission of minor details does not cause a specification to fail to meet the enablement. However, when there is **no disclosure of** any specific starting material or **any of the conditions under which a process can be carried out, undue experimentation is required**; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. (emphasis added)

Additionally, claims 48 and 49 require nucleotide sequences encoding heavy and light chains of the 2F5 monoclonal antibody. The application discloses an exogenous nucleotide sequences encoding heavy and light chains of the 2F5 monoclonal antibody that is encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention since the sequence are recited in claims 48 and 49, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809. The specification indicates that the source of these nucleotide sequences are either the 2F5 hybridoma or plasmids pTG2676 (light chain) and pTG2677 (heavy chain). While the specification discloses primers that could be used to produce the nucleotide sequences by PCR from either the hybridoma mRNA or the plasmids, it does not provide the

sequence of these nucleotide sequences. Consequently, the only reproducible method disclosed requires either the hybridoma or the plasmids as a source of template nucleotide sequences.

It is unclear whether the hybridoma or plasmids are known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material, either of the hybridoma or of plasmids pTG2676 and pTG2677. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 41, 43-48, and 51-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 and claims dependent thereon are indefinite for recitation of "said antibody is modified by a ... immunopotentiating substance". The scope of "immunopotentiating substance" is unclear, as is the nature of the modification to the antibody by the substance. The specification does not clearly define what is meant either by "modified by" or "immunopotentiating substance" in this context. The examples provided are limited to an exogenous nucleotide sequence encoding a fusion polypeptide comprising part or all of an antibody chain and another polypeptide, e.g. a toxic protein, prodrug activating enzyme, CD4 soluble domain, or an FcγR. In this context, the antibody is modified with a second polypeptide, not "by" the polypeptide. As written, the claim implies that the substance acts on the antibody to modify it. The disclosed examples of "immunopotentiating substance" are a CD4 soluble domain or an FcγR, these two proteins do not provide one with sufficient information for one of skill in the art to determine what other modifications to an antibody would be excluded or included by the claim.

Regarding claims 44 and its dependents, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The metes and bounds of claim 48 are unclear. Claim 40 requires an exogenous nucleotide sequence which encodes an antibody modified by an immunopotentiating substance. It is unclear if the 2F5 antibody recited in claim 48 is the antibody of claim 40, or if the exogenous nucleotide sequence of claim 48 is a second, separate exogenous nucleotide sequence present in the vector.

Claims 51 and 58 recite the limitation "the infected cells" at the end of each claim. There is insufficient antecedent basis for this limitation in the claim. Also, these claims recite the phrase "promoter which is specifically active" in a tumor or infected cell. The meaning of "specifically active" is not defined in the specification and it is unclear how or if this limits the scope of a "promoter" beyond a promoter active in tumor or infected cells.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40, 41, 43-47, 51-58 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kolls et al. (Proc. Natl. Acad. Sci. USA 91: 215-219, Jan. 1994).

Kolls discloses a replication defective adenoviral vector which comprises an exogenous nucleotide sequence in place of map units 1.3-9 of Ad5. The exogenous nucleotide sequence encodes a fusion protein comprising part of an antibody (conserved domains of an IgG heavy chain) fused to the extracellular domain of tumor necrosis factor receptor, which fusion protein forms a homodimer when expressed. Kolls also discloses adenoviral particles comprising the vector, HEK 293 cells infected with the vector, and an injectable pharmaceutical composition comprising between 10^7 and 10^9 pfu of the particles. See entire document, especially page 215, page 216, bottom of col. 2, page 219, col. 1, second full para.). As clearly seen in Kolls, TNF-R is an "immunopotentiating substance." The CMV promoter used is active in cells infected by the adenoviral vector, and is known to function in tumor cells.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 40, 41, 43-47, and 51-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allaway et al. (WO 94/19017) in view of Berkner (WO 90/01550).

Allaway discloses plasmid vectors and cells comprising same for the production of a chimeric antibodies comprising a CD4 extracellular domain (sCD4) including the CD4 leader peptide. Several types of expression construct are disclosed, the antibodies can be a homodimer of a sCD4 fused to the constant region of an IgG1 or IgG2 heavy chain, or a heterotetramer of a sCD4 fused to the constant region of an IgG1 or IgG2 heavy chain and kappa or lambda light chains or sCD4 fused to one of the light chains. See page 9, line 32 to page 10, line 31; page 17, line 10 to page 18, line 18; page 24, line 21, through page 30. Allaway does not disclose using adenoviral vectors to produce the chimeric antibodies.

However, Berkner had disclosed the construction of replication-defective adenoviral vectors (deletion of E1) for the expression of multimeric proteins, such as immunoglobulins, and eukaryotic host cells and viral particles comprising same. The vectors comprised an exogenous nucleotide sequence comprised a polycistronic transcription unit operably linked to expression sequences, promoters including the MLP promoter and SV40 early promoter, viral leader sequences such as the adenoviral tripartite leader located between the cistrons (and optionally a leader upstream of the first cistron) and polyadenylation sequences. Berkner dislcoses that the polycistronic vecotr system has the advantage over prior art multiple plasmid-based systems (such as that used by Allaway) in that only one vector need be used, rather than separate vectors for each subunit. This advantage avoids the necessity of using several different marker genes, and

the limitation of choice of host cell (dictated by the marker genes), and is more efficient in producing desired transfectants since co-transfection of multiple vectors is less efficient than transfection of a single vector. Polycistronic adenoviral vectors have the advantage over plasmids in their ability to transfect all cells of a culture (or *in vivo*), i.e. a much higher transfection efficiency. See pages 4-8; page 10, line 2 to page 11, line 15; page 13, line 1 to page 14, line 26.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the multiple plasmid vectors of Allaway separately encoding the heavy and light chain subunits with a single replication deficient adenoviral vector with the chimeric heavy and or light chains encoded by a single polycistronic construct, as taught by Berkner. One would have been motivated to do so for the advantages explicitly disclosed in Berkner, e.g. higher efficiency of transfection. One of skill in the art would also have been motivated to replace the single plasmid vector of Allaway encoding the chimeric heavy chain antibody with a replication defective adenovirus comprising a monocistronic construct encoding the antibody to take advantage of the higher transfection efficiency of adenoviral vectors. The term "pharmaceutical" recited in claim 54 refers to an intended use for the adenovirus which does not distinguish the composition form one that would be used in cell culture for example.

Allowable Subject Matter

Claims 49 and 50 are free of the prior art. Allaway discloses using chimeric sCD4-IgG fusion proteins in combination with 2F5 antibodies, but does not disclose using 2F5 heavy chain sequences in the fusion proteins, nor does it provide any suggestion or motivation to do so.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe

Scott D. Priebe, Ph.D.
Primary Examiner
Technology Center 1600
Art Unit 1632

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL ATTACHMENT

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).

5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.